

REMARKS

This Amendment is in response to the Office Action mailed on February 17, 2006. In that Office Action, claims 1-15 were rejected. In this Amendment, claim 1 has been amended, and no new claims have been added.

On Page 2 of the Office Action, the Office Action states the information disclosure statement filed on October 20, 2003 fails to comply with 37 C.R.R. 1.98(a)(2) which requires a legible copy of each cited foreign patent document, each non-patent literature publication or that portion which caused it to be listed and all other information or that portion which caused it to be listed.

Legible copies of each non-patent literature publication or the corresponding portion are attached (Shrivastava et al. 1993; Souccar and Curtay 1996 and Dupin et al. 1999) as well as that of each foreign patent document cited. Consideration of each document is therefore respectfully requested.

Claim Rejections Under 35 U.S.C. §102

On Page 2 of the Office Action, claims 1-9 and 13-15 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S Patent No. 4,237,118, issued to Howard hereinafter referred to as the "Howard 118 reference". On page 4 of the Office Action, claims 1-9 were rejected under 35 U.S.C. 102(b) as allegedly being anticipated by U.S. Patent No. 4,009,265, issued to Howard, hereinafter referred to as the Howard 265 reference". On page 5, claims 1-3 and 13-15 were rejected under 35 U.S.C. 102(b) as allegedly being anticipated by U. S. Patent No. 5,571,441 hereinafter referred to as the "Andon reference". On page 6, claims 1, 2, 4, 5, 7, 8, 10, 11 and 13-15 were rejected under 35 U.S.C.102(b) as allegedly being anticipated by G.B Patent No. 2,038,157 issued to Saiki et al, hereinafter referred to as the "Saiki reference".

The Office Action states the Howard 118 reference discloses a composition in the form of a nutritional product comprising vitamin A, folic acid, vitamin E and magnesium and zinc for the treatment of obesity while the Howard 265 reference discloses methods and formulations containing vitamin A, riboflavin, folic acid, magnesium, zinc and an emulsifier polyoxyethylene sorbitan monooleate, normally administered in water for a total caloric value of a daily diet that

is in the range of 160 to 600 kcals for the treatment of obesity. The Office Action also states the Andon reference discloses a nutritional supplement composition containing vitamin A, riboflavin, zinc, copper, magnesium stearate (a pharmaceutically acceptable excipient) and caffeine. In addition, the Office Action states the Saiki reference discloses a food composition for the manufacture of foods capable of reducing caloric intake to minimum requirements that includes vitamin A, B2, vitamin E, folic acid, zinc and magnesium and admixed with a non-nutritional carrier (an excipient). The Office Action also states an example in the Saiki reference discloses providing the food to subjects and the subjects performing daily exercise simulating bicycle riding and the diet of the test group being 10% lower or a hypocaloric diet when compared to the control group.

The Office Action further states the Howard 118 reference, the Howard 265 reference, the Andon reference and the Saiki reference do not teach reduction of intracellular lipids and toxic wastes which have accumulated in a human body and the intended use of the claimed composition is inherent in the reference composition. The Office Action further suggests that in order for the claimed composition to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. Applicant respectfully disagrees with these statements.

As noted, claim 1 has been amended. Before responding to the rejections, a review of the invention will be provided. One important discovery described in the patent application is the effects of a highly specific association or combination of two vitamins of vitamins A, E, B2 and B9 and two minerals from copper, selenium, zinc and magnesium that act synergistically to reduce intracellular lipid levels. It is the truly specific nature of the vitamins and minerals that creates the previously unknown synergism and which distinguishes the present invention from others. If the association or combination is incorrect, no effect or reduction in intracellular lipid levels occurs. Consequently, claim 1 in its amended form is believed to create a structural difference between the claimed composition and the prior art compositions.

Claim 1 defines a composition consisting of at least two vitamins of vitamin A, B2, B9 or E along with at least two minerals of magnesium, zinc, copper and selenium that is effective

to reduce intracellular lipid levels. On the other hand, the Howard 118 reference describes a dietary supplement for use with 61.3 to 123 grams of dried skimmed milk in the dietary regime which contains a variety of minerals and trace elements such as iron (18 ± 9 mg), sodium (182 mg), potassium (308 mg), magnesium (>64 mg), Vitamin A (>750 mg), Vitamin D (100 IU), thiamine (0.76 mg), ascorbic acid (18 mg) with a total caloric content not exceeding 200 kcal. See for example, column 3, lines 47-51, column 4, lines 54-63 of the Howard 118 reference. The supplement of the Howard 118 reference also contains iodine (50-150 mg), phosphorus (>15 mg) and trace amounts of copper, zinc, manganese, Vitamin B6, B12, E, K, folic acid, riboflavin, pantothenic acid, d-biotin and choline. See the Abstract of the Howard 118 reference. Therefore, the Howard 118 reference discloses supplementation of dried skimmed milk with vitamins, minerals and trace elements in order to compensate for the lack of these vitamins and minerals in a low caloric diet. Hence, the composition of the Howard reference is a non-specific dietary supplement that can be used in a method of treating obesity and not a specific synergetic composition of vitamins, minerals and trace-elements that is effective to reduce intracellular lipid levels.

The Howard 118 reference does not disclose that the supplement is effective to reduce intracellular lipid levels as disclosed in the present invention. The dietary supplement described in the Howard 118 reference has no demonstrated effect on intracellular lipids, and consequently cannot be considered to enhance intracellular lipid elimination.

Since the supplement of the Howard 118 reference does not disclose the specific combination of at least two of vitamins A, E B2 and B9 along with at least two of copper, selenium, zinc and magnesium as being effective to reduce intracellular lipids, the Howard 118 reference does not anticipate the present invention as defined in independent amended claim 1. It is believed that claim 1 is in allowable form. Since claims 2-15 depend from claim 1, it is believed claims 2-15 are also in allowable form. Therefore, reconsideration and allowance of all the claims are respectfully requested.

Next, the Howard 265 reference discloses formulations containing all of the vitamins required by human beings in association with proteins, digestible carbohydrates and amino acids

during the period of attempted weight reduction by dietary restriction. According to the Howard 265 reference, dietary restriction also restricts supplies to the body of all essential elements including vitamins, minerals and trace elements in addition to proteins, fats and carbohydrates.

However, the non-specific compositions described in the Howard 265 reference are not aimed at reducing intracellular lipid accumulation and contain most essential elements along with carbohydrates, amino acids and proteins. No synergetic effects of vitamins and minerals in the composition of the Howard 265 reference on intracellular lipid accumulation are shown. Rather, the formulations of the Howard 265 reference function to reduce adverse consequences of dietary restrictions during weight loss attempts, in particular to supply the daily requirements of essential elements which are otherwise reduced by dieting, but these compositions have no direct effect *per se* on weight loss or obesity. Therefore, the Howard patent does not anticipate pending claims 19 in their present form.

Additionally, the Andon reference discloses nutritional supplement compositions that contain vitamins, minerals and caffeine useful for compositions providing physiologic feedback. The compositions disclosed in the Andon reference are useful in promoting regular consumption of nutritional supplements used for improving diet and are not intended for weight loss, treatment of obesity or cholesterol reduction.

The compositions described in the Andon reference contain a combination of nearly all vitamins and essential minerals rather than the specific combination of at least two of vitamins A, E, B2 and B9, and at least two of copper, magnesium, selenium and zinc. Therefore, the compositions of the Andon reference have no specific effect on reducing intracellular lipid accumulation.

On the other hand, the claim 1 defines the present invention as the combination consisting of at least two of vitamins A, E, B2 and B9 along with at least two of copper, selenium, zinc and magnesium are effective in reducing intracellular lipid accumulation. Therefore, the Andon reference does not anticipate the present invention as now defined in pending claims 1-3 and 13-15.

Regarding the rejection of claims 1, 2, 4, 5, 7, 8, 10, 11 and 13-15 based on the Saiki reference, the Saiki reference discloses a food composition that includes not only vitamins and minerals but also proteins, caloric sources and foods. Low caloric diets/foods employed in weight reduction programs are often associated with vitamins, minerals, and amino acids to compensate for their deficiency. Fat loss is known to be accelerated by exercise. Nevertheless, the Saiki reference does not disclose the present invention since the methods and food compositions do not describe the effect of combining at least two of vitamins A, E, B2 and B9 along with at least two of copper, selenium, magnesium and zinc. In addition, the Saiki reference does not under any circumstances take into account cellular activities and there is no influence on the cellular functions which eliminate intracellular lipid deposits.

As noted, the present invention describes a scientifically proven association of only two of four selected vitamins and minerals, in an amount which can stimulate cellular function (intracellular lipid elimination). If the correct association is not used, no effects on intracellular lipid elimination are observed. Therefore, combining several vitamins and essential minerals in a non-specific composition has no effect on intracellular lipids, as our results prove.

It is believed claims 1, 2, 4, 5, 7, 8, 10, 11 and 13-15 are in allowable form. Therefore, reconsideration and allowance of claims 1, 2, 4, 5, 7, 8, 10, 11 and 13-15 are respectfully requested.

Claim Rejections Under 35 U.S.C. §103

On page 7, claims 1-6 and 10-12 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the Howard 118 reference in view of the document disclosed in Nutrition 2000, 16, 179-188, hereinafter referred to as the "Votruba reference". According to the Examiner:

"Votruba et al provide a general teaching that exercise is strongly associated with improved weight maintenance (Page 187, left column first paragraph). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to include exercise as suggested by Votruba et al with the method of treating obesity of Howard for the purpose of losing weight and keeping it off and produce the instant invention

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole would have been fairly disclosed or suggested by the combined teachings of the cited references.”

With all due respect, Applicant respectfully disagrees with the Examiner rejections and statements. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Applicant would like to address the first criteria without acknowledging that the second and third criteria have been met, since applicant believes that only a discussion of the first criteria is necessary to obviate the rejection under 35 U.S.C. § 103(a).

As noted above, the Howard 118 reference describes a dietary supplement for use with 61.3 to 123 grams of dried skimmed milk in the dietary regime which contains a variety of minerals and trace elements such as iron, sodium, potassium, magnesium, Vitamin A, Vitamin D, thiamine, ascorbic acid with a total caloric content not exceeding 200 kcal. See for example, column 3, lines 47-51, column 4, lines 54-63 of the Howard 118 reference. The supplement of the Howard 118 reference also contains iodine, phosphorus and trace amounts of copper, zinc, manganese, Vitamin B6, B12, E, K, folic acid, riboflavin, pantothenic acid, d-biotin and choline. See the Abstract of the Howard 118 reference. Therefore, the Howard 118 reference discloses supplementation of dried skimmed milk with vitamins, minerals and trace elements in order to compensate for the lack of these vitamins and minerals in a low caloric diet. Hence, the composition of the Howard reference is a non-specific dietary supplement that can be used in a method of treating obesity and not a specific synergetic composition of vitamins, minerals and trace-elements that is effective to reduce intracellular lipid levels.

The Votruba reference describes the role of exercise in the treatment of obesity and shows that exercise *per se* has no effect on body weight. The authors of the Votruba reference suggest that weight loss attempts should include exercise along with reduced energy intake. Nevertheless, the Votruba reference does not mention the role of vitamins and minerals, or any specific association of vitamins and minerals in reducing intracellular lipids. Therefore, the conclusions of the study in the Votruba reference are totally unrelated to those claimed in this application.

As noted, the combination consisting of at least two of vitamins A, E, B2 and B9 along with at least two of copper, zinc, magnesium and selenium are effective in reducing intracellular lipids and are compatible with and may be used concomitantly with reduced caloric intake or exercise. There must be a reason or suggestion in the art for selecting the procedure used other than the knowledge learned from applicant's disclosure. *In re Dow Chemical*, 5 U.S.P.Q. 2d 1529, 1532 (CAFC 1988). There is no suggestion in the Howard 118 reference to modify the vitamin and minerals disclosed in the Howard 118 reference to reduce intracellular lipid levels. There is also no suggestion in the Votruba reference to consume any vitamins and minerals, much less the combination of at least two of vitamins A, E, B2 and B9 along with at least two of copper, selenium, zinc and magnesium to reduce intracellular lipid levels. Therefore, the Howard 118 reference in combination with the Votruba reference does not teach or disclose the present invention as defined in pending claims 1-6 and 10-12.

It is believed that claims 1-6, and 10-12 are in allowable form. Therefore, reconsideration and allowance of claims 1-6 and 10-12 are respectfully requested.

In view of the above, it is believed that the claims are now all in allowable form. Reconsideration and allowance of all the claims are respectfully requested.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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